Results of second-time angioplasty and stenting for femoropopliteal occlusive disease and factors affecting outcomes

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Objective: **Repeat percutaneous endoluminal interventions for femoropopliteal occlusive disease are common, but the outcomes are poorly understood. We sought to determine the results of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS) and identify factors associated with success or failure of a continued endoluminal revascularization strategy.**

Methods: **A retrospective review of patients undergoing multiple percutaneous endoluminal lower extremity interventions at a single institution from 2002 and 2009 identified 70 SPTAS in 70 limbs. Patient comorbidities, anatomic severity of disease, and procedural characteristics were analyzed with respect to outcomes with descriptive statistics, Kaplan-Meier curves, and Cox proportional hazards modeling. Patency rates were determined from the time of SPTAS.**

Results: **Patients included 37 men (63%) and 22 women (27%) at a mean age of 70 ± 10 years. Indications for SPTAS included claudication in 54 limbs (77%) and critical limb ischemia (CLI) in 16 (23%). Median time from the initial endoluminal intervention to SPTAS was 330 days. Lesion TransAtlantic InterSociety Consensus II (TASCII) classification was A in 18 (25.7%), B in 18 (25.7%), C in 25 (35.7%), and D in 9 (12.9%). Technical success was achieved in 68 (97%) with low rates of intraprocedural (10%) and postprocedural (4%) complications as well as initial clinical improvement in 61 (87%) patients. Over a median follow-up of 22.9 months following SPTAS, 2-year primary patency, secondary patency, limb salvage (in patients with CLI), and survival were 33% ± 7%, 63% ± 7%, 87% ± 9%, and 88% ± 5%, respectively. Cox proportional hazard modeling showed that SPTAS within 180 days of the initial endovascular intervention was the only significant predictor of failure of primary patency (hazard ratio, 2.65; 95% confidence interval, 1.4-5.2) and secondary patency (hazard ratio, 3.1; 95% confidence interval, 1.4-7.1) of SPTAS.**

Conclusions: **Second-time femoropopliteal angioplasty/stenting has excellent technical success but limited midterm primary and secondary patency. Early failure of the initial endovascular intervention strongly predicts poor outcome following SPTAS and in this cohort was more significant than comorbidities, anatomic factors, or procedural characteristics. These data suggest that after early endovascular failure, alternatives to a continued endoluminal strategy should be adopted. (J Vasc Surg 2011;53:651-7.)**

The utilization of endovascular interventions for lower extremity ischemia has increased by more than 300% in the past decade.[1] Percutaneous transluminal angioplasty with or without stenting has emerged in many centers as a first-line therapy for infrainguinal arterial occlusive disease, with the majority of interventions performed in the femoropopliteal segment. The minimally invasive nature of endoluminal intervention makes it extremely attractive initial therapy to patients and physicians alike.

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However, the durability of endovascular therapy is of major concern, with primary patency of angioplasty with or without stenting reported to be 47% to 75% at 1 year, 42% to 60% at 3 years, and 26% to 52% at 5 years.[2-7] Accordingly, a significant portion of endoluminal revascularizations may require secondary interventions due to failure of the initial procedure. However, the outcomes of second-time percutaneous transluminal angioplasty with or without stenting (SPTAS) are not known. Furthermore, the patient, anatomic, and procedural characteristics associated with the outcome of SPTAS have not been described. The literature currently offers only indirect information on the success of secondary endovascular procedures. Primary assisted and secondary patency of primary endovascular interventions is reported to be 55% to 75% at 18 months to 3 years.[4,5,7] There may be an implicit belief that the second intervention, if required, will be at least as successful as the initial intervention, and this assumption seems to be driving the promulgation of endovascular therapy for infrainguinal occlusive disease. In addition, methodologic problems in much of the current endovascular literature make it difficult to evaluate the effectiveness of repeat interventions. Reports often focus on the need for "target lesion revascularization", which is both prone to significant subjectivity and

fails to address the more clinically relevant issue of the need to revascularize the same arterial segment due to evidence of insufficient or jeopardized flow. Variations in the reporting of patency criteria, patient follow-up, and surveillance further hinder the assessment of the outcomes of secondary endovascular interventions.

Vascular surgeons and other interventionalists will increasingly face decisions regarding the relative utility of continued endovascular intervention vs alternative strategies such as medical therapy and surgical bypass. The goal of this study was to determine the results of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS) and identify the factors associated with outcome.

METHODS

Patients and procedures. All patients undergoing lower extremity diagnostic or interventional procedures at the Brigham and Women's Hospital are prospectively entered into our clinical database. Our database was searched for patients who underwent lower extremity angiography and/or intervention between January 2002 and April 2009. Patients whose procedural coding included more than one occurrence of the current procedural terminology (CPT) codes 35474 (femoral or popliteal percutaneous transluminal angioplasty [PTA]) or 37205/37206 (placement of intravascular stent) were identified as patients who potentially underwent repeat femoropopliteal endovascular intervention. We completed a detailed review of these patients' charts and all angiograms of procedures to identify occurrences of repeat angioplasty or stenting on a previously treated femoropopliteal segment. We defined this as SPTAS. Indications, patient comorbidities, medication usage, and time from the initial failed intervention and SPTAS were obtained from chart abstraction. Anatomic characteristics of both SPTAS and initial endovascular interventions including TransAtlantic InterSociety Consensus II (TASCII) classification, presence of a total occlusion, presence of in-stent restenosis, and runoff score were determined by detailed review of angiograms.

Endovascular technique and surveillance of endovascular interventions. All interventions were performed percutaneously by either vascular surgeons or interventional cardiologists in the catheterization lab at Brigham and Women's Hospital. Techniques were at the discretion of the operator but generally involved antegrade approach via contralateral femoral access. Both .035 and .014 platforms were utilized for angioplasty with or without stenting depending on operator preference. Use of stents included both selective stenting as indicated for residual stenosis or flow-limiting dissection and primary stenting according to operator discretion. Surveillance of revascularizations was generally done with clinical examination, ankle-brachial indices (ABIs), and duplex ultrasonography at 1, 3 to 6, and 12 months, followed by testing yearly or as required.

Outcomes. Patency rates were determined from the time of SPTAS, which was the index procedure in this study. Primary patency and secondary patency rates were defined in accordance with the suggested reporting standards of the Society for Vascular Surgery/International Society for Cardiovascular Surgery Ad Hoc Committee.[8] All revascularizations were evaluated via objective criteria including duplex ultrasonography or contrast arteriography in 62 (88.6%) and maintenance of an ABI in eight (11.44%). Failure of patency was defined by either the need for endovascular reintervention to maintain patency or a drop in ABI $>$ .1 since the highest postintervention index.[8] Criteria for reintervention were recurrent symptoms in conjunction with $\geq$75% stenosis (3:1 velocity increase in our laboratory) of a previously treated segment accessed via duplex or angiogram. Early failure of the initial endovascular intervention was defined as need for SPTAS within 180 days of the initial endovascular intervention. Limb salvage was defined as freedom from transtibial or above-knee amputation.

Statistical analysis. Descriptive statistics were used to analyze comorbidities, anatomic, and procedural characteristics. Continuous variables were compared using the Student *t*-test and categorical variables were compared using a χ^2 test or Fisher's exact test where numbers in each group were small. Ordinal variables were compared between groups using a Mantel-Haensel χ^2 trend test. Primary and secondary patency, limb salvage, and patient survival rates were analyzed with Kaplan-Meier curves and the log-rank test. Univariate and multivariable analysis of patient demographics and comorbidities, anatomic variables, and procedural factors associated with outcomes were performed with a Cox proportional hazards model. Variables associated with outcome on univariate analysis ($P \leq .2$) were included in the multivariable regression model to identify factors independently associated with outcome. An α value of .05, corresponding to $P = .05$ and 95% confidence intervals (CIs), was used as a criterion for statistical significance. Statistical computations were performed with SAS v9.1 (Cary, NC).

RESULTS

Demographics, indications, and comorbidities. From January 1, 2002 to April 1, 2009, 70 SPTAS were performed in 59 patients. The indication at SPTAS was claudication in 54 (77%) and critical limb ischemia (CLI) in 16 (23%). Claudication was the indication for initial endovascular intervention in 59 (84%) limbs. Patients were primarily Caucasian with a high prevalence of associated comorbidities (Table I). The median (interquartile range) time between the initial endovascular intervention and SPTAS was 330 (range, 196-582) days. Sixteen SPTAS (23%) were performed after early failure of the initial endovascular intervention, which was defined as SPTAS within 180 days of the initial intervention. There were no differences in comorbidities or indications between SPTAS performed after early failure of the initial procedure and those that were not.

Anatomic characteristics of lesions. TASC II classification, the presence of total occlusions, in-stent restenosis, and new lesions in the femoropopliteal segment at SPTAS

Table I. Demographics, comorbidites, and indications

	n (%)
Age	70.1 ± 9.5 (50-90)
Male	37 (62.7%)
Race (Caucasian)	55 (94.8%)
Diabetes	19 (32.2%)
HTN	54 (91.5%)
Hyperlipidemia	54 (91.5%)
CAD	36 (61%)
CHF	9 (15.3%)
Smoker	16 (27.1%)
CRI	4 (6.8%)
Dialysis	0 (0)
CR	1.1 ± .47 (0-3.2)
Indication	
Claudication	54 (77.1%)
Rest pain	10 (14.3%)
Ulcer	4 (5.7%)
Gangrene	2 (2.9%)

CAD, Coronary artery disease; *CHF*, congestive heart failure; *CR*, creatinine; *CRI*, chronic renal insufficiency; *HTN*, hypertension.

Table II. Anatomic characteristics of femoropopliteal lesions treated at second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS)

	n (%)
TASC II classification	
A	18 (25.7%)
B	18 (25.7%)
C	25 (35.7%)
D	9 (12.9%)
Total occlusion	23 (32.9%)
In-stent restenosis	41 (58.6%)
Restenosis at PTA site	17 (24%)
New lesion	12 (17.14%)

PTA, Percutaneous transluminal angioplasty; *TASC II*, TransAtlantic InterSociety Consensus II.

are outlined in Table II. There were no differences in anatomic severity of lesions at SPTAS with regards to TASC level, presence of total occlusion, and run-off score between those undergoing SPTAS within 6 months or after 6 months from the initial endovascular failure.

Anatomic characteristics of lesions at the time of the initial endovascular intervention are outlined in Table III. There were no significant differences in TASC II classification, percentage of total occlusions, and number of runoff vessels at initial intervention as compared with SPTAS. In addition, there were no significant differences in anatomic characteristics of initial endoluminal interventions that failed within 6 months and those that failed after 6 months (data not shown). Stenting was performed in 41 limbs (59%), while PTA without stenting was performed in 29 (41%) at the initial intervention. Fifty initial interventions (71%) involved simultaneous iliac or tibial intervention. Plavix was utilized in 66 (96%) of interventions.

The causes of failure of the initial endovascular intervention were in-stent restenosis in 41 (59%), restenosis after previous PTA alone in 17 (24%), and progression of disease with new lesions in 12 patients (17%). Among those experiencing early failure of the initial endovascular intervention, eight patients (50%) had failure after PTA alone, seven patients (44%) experienced in-stent restenosis, and one (6%) patient was characterized as having a new lesion not previously treated in the femoropopliteal segment. The mode of failure of the initial endovascular intervention was not significantly different among those experiencing failure before 6 months and after 6 months.

Table III. Anatomic and procedural characteristics of the initial endovascular intervention

	n (%)
TASC II classification	
A	13 (20.3%)
B	14 (21.9%)
C	29 (45.3%)
D	8 (12.5%)
Total occlusion	24 (37.5%)
Runoff vessels	
0	1 (1.6%)
1	10 (15.9%)
2	32 (50.8%)
3	20 (31.8%)
Stent placement	41 (58.6%)

TASC II, TransAtlantic InterSociety Consensus II.

Procedural characteristics of SPTAS. Forty-two SPTAS (60%) included angioplasty without stenting while intravascular stenting was performed in 28 procedures (40%). Adjunctive therapy was utilized to supplement angioplasty ± stenting in 32 procedures (45.7%) and included rotational and laser atherectomy, cryoplasty, and brachytherapy. Twenty-two procedures (31%) involved treatment of the femoropopliteal segment only, while 47 procedures (67%) involved concomitant treatment of either an iliac or tibial lesion. In one procedure, lesions in each of the three levels were treated. Concomitant lesions treated as well as the number of runoff vessels in continuity to the level of the ankle at completion of SPTAS are outlined in Table IV.

Early results. SPTAS was performed with excellent technical success and a low rate of periprocedural complications (Table V). Sixty-one (87%) of patients reported clinical improvement at the first postoperative visit, and the average increase in ABI at 1 month was .25 ± .31. SPTAS performed after early failure of initial endovascular therapy was associated with lower rate of reported improvement at the first postprocedure visit (69% vs 93%; $P = .02$) and increased intraprocedural complications (25% vs 6%; $P = .044$) although there was no difference in rate of technical success in comparison to those without early failure (100% vs 96%; P = NS). Use of heparin or warfarin in (25% vs 11%; P = NS) or clopidogrel (88% vs 98%; P = NS) was not different following SPTAS performed after early failure of initial endovascular therapy as compared with SPTAS without early failure.

Outcomes of SPTAS. Overall, 2-year primary patency was 33.2% (Fig 1). Over the course of follow-up, there were

Table IV. Procedural characteristics of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS)

	n (%)
Levels treated	
Femoropopliteal only	22 (31.4%)
Femoropopliteal and iliac or tibial	47 (67.1%)
Femoropopliteal, iliac, and tibial	1 (1.4%)
Iliac intervention	38 (54.3%)
Tibial intervention	11 (15.7%)
Stent placement	28 (40%)
Adjunctive therapy	32 (45.7%)
Runoff vessels	
1	15 (21.7%)
2	33 (47.8%)
3	21 (30.4%)

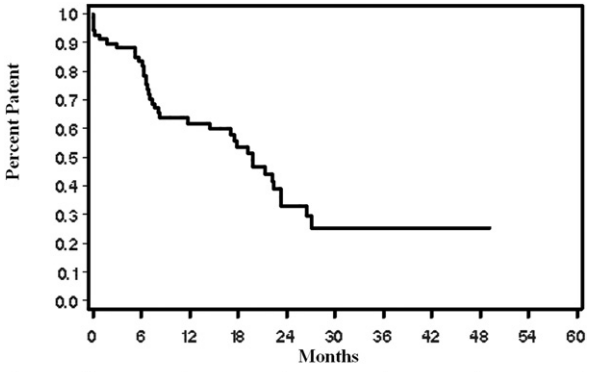
Table V. Early results of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS)

	n (%)
Technical success	68 (97.1%)
Procedure complication	
Access	1 (1.4%)
Embolism	1 (1.4%)
Dissection	5 (7.1%)
Postprocedure complication	
MI/stroke	0/0
ARF	1 (1.4%)
Bleeding	2 (2.86%)
Discharge Plavix	67 (95.7%)
Discharge anticoagulation	10 (14.3%)
Discharge statin	58 (82.9%)
Improved at first visit	61 (87.1%)
Worse at first visit	2 (2.9%)
Change in ABI	.25 ± .31 (−.63-1.22)
Median LOS	1 day

ABI, Ankle-brachial index; *ARF*, acute renal failure; *LOS*, length of stay; *MI*, myocardial infarction.

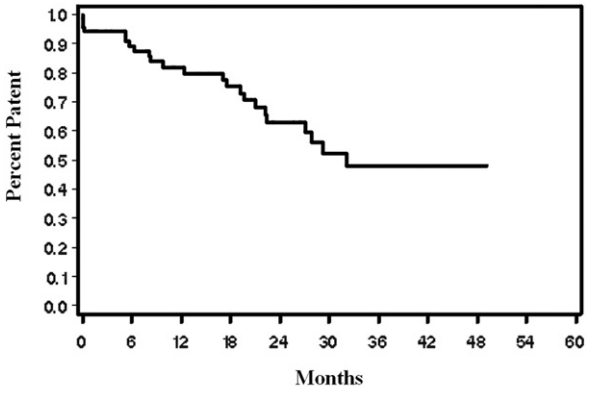
39 failures of primary patency of SPTAS. Of these 39, 31 patients underwent further revascularization. Twenty-seven patients underwent endovascular reintervention (the third endovascular intervention in the femoropopliteal segment) after failed SPTAS. Secondary patency of SPTAS was 63% (Fig 2). Four patients underwent surgical bypass, and eight had no reintervention.

Eight failures of SPTAS occurred in 16 patients who underwent SPTAS for CLI, resulting in a primary patency of 50%. There were no amputations performed in patients with patent SPTAS. Of those who failed, six underwent additional revascularization. A third endovascular femoropopliteal intervention was performed in four limbs. Two patients underwent femoral-distal bypass grafting. One patient progressed to below-knee amputation 3 months after surgical bypass. One patient was judged not to have a surgical bypass option and underwent amputation after failed SPTAS. In those undergoing SPTAS for CLI, 2-year limb salvage was 86.5%. The remaining 31 failures of



Months	0	12	24	36	48
No. at Risk	70	32	11	5	3
SE	0	.06	.07	.07	.07

Fig 1. Primary patency of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS). The number at risk and associated standard error (*SE*) at yearly time intervals are shown in the table below each curve.

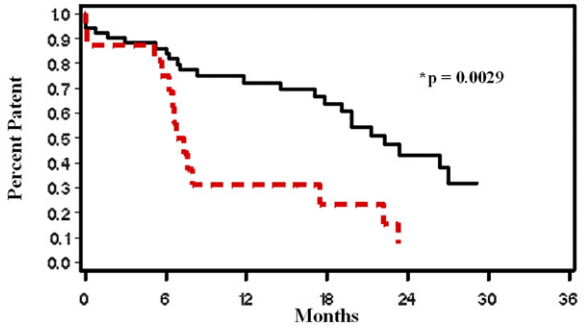


Months	0	12	24	36	48
No. at Risk	70	40	22	9	3
SE	0	.05	.07	.09	.09

Fig 2. Secondary patency of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS). The number at risk and associated standard error (*SE*) at yearly time intervals are shown in the table below each curve.

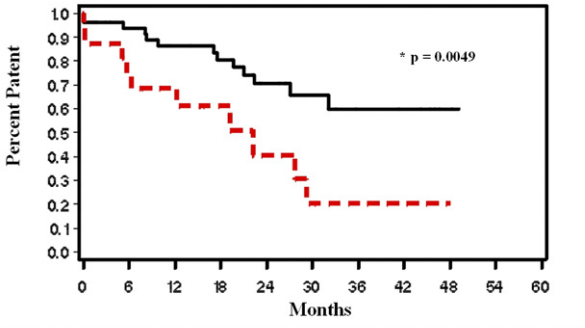
SPTAS occurred in patients undergoing SPTAS for claudication. Of these failures, 25 limbs underwent additional revascularization. A third endovascular intervention was performed in 23 limbs. Twelve remained patient for a secondary patency of SPTAS of 53%. Two patients underwent surgical bypass. There were no amputations in patients undergoing SPTAS for claudication. Overall 2- and 3-year survival were 88.5% and 83%, respectively.

Univariate analysis including demographics, comorbidities, and timing of SPTAS, anatomic and procedural



No Early Failure	0 mo	6 mo	12 mo	18 mo	24 mo	30 mo
No. at Risk	54	39	27	22	10	4
SE	0	.05	.07	.07	.09	.1
Early Failure						
No. at Risk	16	12	5	3	1	1
SE	0	.1	.11	.11	.07	.07

Fig 3. Impact of early endovascular failure on primary patency of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS). Primary patency of SPTAS of those with early failure of the initial endovascular intervention (*dashed line*) vs those without early failure of the initial endovascular intervention (*solid line*), log-rank test; $P = .0029$. *SE*, Standard error.



No Early Failure	0 mo	6 mo	12 mo	18 mo	24 mo	30 mo
No. at Risk	54	41	31	27	19	12
SE	0	.03	.05	.06	.08	.09
Early Failure						
No. at Risk	16	12	9	6	4	2
SE	0	.1	.12	.13	.14	.12

Fig 4. Impact of early endovascular failure on secondary patency of second-time femoropopliteal percutaneous transluminal angioplasty/stenting (SPTAS). Secondary patency of SPTAS of those with early failure of the initial endovascular intervention (*dashed line*) vs those without early failure of the initial endovascular intervention (*solid line*), log-rank test; $P = .0049$. *SE*, Standard error.

characteristics of both SPTAS and the initial endovascular intervention was performed to identify factors associated with failure of patency of SPTAS. Only the use of clopidogrel after SPTAS (hazard ratio [HR], .28; 95% CI, .083-.95) and SPTAS within 6 months of initial endovascular intervention (HR, 2.7; 95% CI, 1.4-5.2) showed significant effect on failed primary patency of SPTAS. On multivariable analysis, only early failure (<180 days) of the initial endovascular intervention was a significant predictor of failed primary patency of SPTAS (2-year primary patency: SPTAS within 6 months of initial procedure, 7.8 ± 7.4%, vs SPTAS more than 6 months from initial procedure, 43 ± 8.7%; HR, 2.7; 95% CI, 1.4-5.2; Fig 3). Likewise, on both univariate and multivariate analysis, early failure (<180 days) of the initial endovascular intervention emerged as the only factor with a significant association with failed secondary patency (2-year secondary patency: SPTAS within 6 months of initial procedure, 60 ± 9.6%, vs SPTAS more than 6 months from initial procedure, 71% ± 7.7%; HR, 3.1; 95% CI, 1.4-7.1; Fig 4).

DISCUSSION

This study provides a novel characterization of the results of SPTAS and the factors predictive of the outcome of SPTAS in the femoropopliteal segment. Short-term outcomes of SPTAS mirror that of primary endovascular interventions. The technical success of SPTAS was 97% with low periprocedural complications is comparable to that reported for first-time endovascular interventions for femoropopliteal occlusive disease.[5,7,9] Short-term efficacy is further evidenced by a median LOS of 1-day and reported clinical improvement by 87% of patients at their first postprocedure visit. The low morbidity and early of success of SPTAS likely reinforces the utilization of repeat endoluminal revascularization for patients and interventionalists alike.

The midterm results, however, of SPTAS are not encouraging and substantially inferior to those generally reported for initial percutaneous transluminal angioplasty with or without stenting. Only 33.2% of SPTAS maintained primary patency at 2 years. With an additional endovascular intervention (a third overall intervention), a 2-year secondary patency SPTAS of 63% could be maintained. This is similar to the experience of Ryer et al who report 84% secondary patency at 1 year and 40% secondary patency after 2 years in 46 patients who failed initial endovascular intervention.[10] Treiman et al, in a study of 35 patients treated for recurrent femoropopliteal stenosis between 1983 and 1993, reported clinical and hemodynamic success of 41% at 1 year, 20% at 2 years, and 11% at 3 years.[11] Despite limited durability, there is no evidence that poor midterm patency portended limb loss, as limb salvage was 86.5% at 2 years in our limited sample of patients with CLI. This is consistent with the 1-year limb salvage rate of 86% reported by Ryer et al. However, the potential impact of failed repeat endovascular intervention on limb salvage in patients with critical limb ischemia requires additional study.

One might expect the determinants of outcome of SPTAS to mimic those of initial femoropopliteal angioplasty ± stenting. Previous studies have identified a variety of factors that influence the success of initial endovascular intervention: gender, diabetes, hyperten-

sion, hyperlipidemia, critical limb ischemia, TASC classification, the need for multilevel intervention, distal runoff status, and stenting.[2-4,9,12-15]

The demographics and comorbidities of patients in this cohort were similar to those of previously published cohorts undergoing first-time infrainguinal angioplasty. As seen in reports from other centers with extensive endovascular experience,[9,12,14,16] the majority of our patients were older males with multiple medical comorbidities. The indication for intervention was claudication in 77% of this cohort, which is slightly higher than other series in which 55% to 70% of lower extremity interventions are undertaken for claudication.[9,12,14,16] This likely reflects a preference for surgical bypass for those with critical limb ischemia by operators at our institution. There was an extremely high prevalence of Caucasians that reflects the demographics of our tertiary referral center.

The anatomic characteristics of lesions at the time of the second endovascular interventions have not been well characterized in the literature. Overall, lesions were of only moderate severity according to TASC II classification. Greater than 50% of SPTAS were performed on TASC A and B lesions. This is consistent with results reported by Joels et al, who found that 81% of 24 limbs requiring reintervention for early failure of endovascular therapy in the superficial femoral artery had TACS A and B disease.[3,4,14,17] In addition, only one-third of lesions treated at SPTAS were total occlusions, and 59% of lesions were areas of in-stent restenosis, suggesting that these reinterventions were often required for limited anatomic disease, most often in previously treated areas. Patency of SPTAS in this cohort was quite limited despite only moderate lesion severity at SPTAS. In fact, lesion severity was not found to predict outcome of SPTAS.

Anatomic severity of disease at the initial endovascular intervention also did not predict outcome. The TASC II classification and percentage of total occlusions at the primary endovascular intervention was not different than that present at SPTAS. Only 12% of lesions were TASC D lesions and 37.5% were total occlusions at initial therapy. These results differ significantly from those of Ryer et al, who reviewed the characteristics of initial failed angioplasty in 46 patients and found that 64% of initial failures had TADC D lesions.[10] Because less severe anatomic severity has been shown to be a positive prognostics factor in first-time endovascular intervention, TASC II recommendations extended the range of severity of lesions that were recommended to be treated via percutaneous therapy.[3,4,11,18] However, our results suggest that there are factors other than anatomic severity of disease that influence the response to endovascular therapy that have yet to be elucidated.

The procedural characteristics of SPTAS have not been well described previously. The majority of patients undergoing SPTAS required multilevel interventions, with concomitant iliac or tibial intervention performed in 69% of cases. By comparison, in series of initial endovascular therapy, 45% to 60% of procedures have been reported to involve multilevel intervention.[5,14] Fifty-nine percent of procedures involved treatment of in-stent restenosis. This is consistent with reports which indicate that stenting is performed in 45% to 65% of initial femoral and popliteal percutaneous interventions.[9,14] Stents were also utilized at SPTAS in 40% of interventions. In addition, SPTAS in this series involved adjunctive procedures such as laser debulking, atherectomy, cryoplasty, and brachytherapy, in 45% of cases. However, neither multilevel intervention, stenting, nor use of adjunctive procedures proved to have an impact on the outcome of SPTAS.

In our multivariate analysis, early failure of the initial endovascular intervention proved to be the only significant predictor of the outcome of SPTAS.[17] Early failure of the primary endovascular intervention portended dismal patency of SPTAS with 7.8% ± 7.4% primary patency and 60% ± 9.6% secondary patency at 2 years. Our results differ significantly with the results of Joels et al, who reported a 79% 1-year patency in 14 patients who underwent repeat endovascular intervention after early endovascular failure, which they defined as failure within 200 days from the time of endovascular intervention.[17] We chose a priori to define "early failure" as failure within 180 days because this provided a consistent definition of "early failure" in comparing this endovascular experience with our previously reviewed experience with revision of failed infrainguinal bypass. We previously discovered that failure of lower extremity bypass within 6 months of initial intervention predicted failure of open revision.[19] The median time to failure of the initial endovascular intervention observed in this cohort (330 days) is consistent with observations from other series. Ryer et al and Derubertis et al reported the mean time to failure of endovascular therapy to be 8.7 months and 8.5 months, respectively.[14,18]

Interestingly, the results of this study mimic those in surgical revision of failed infrainguinal bypass grafting as reported by Nguyen et al in our group.[19] Infrainguinal bypass grafts that required revision within 6 months of initial bypass were more likely to require subsequent revision to maintain patency. The reasons for the detrimental impact of early endovascular failure are not clear. Early failure may represent factors that have not been characterized to this point but which predispose endovascular intervention in that limb to failure. Further investigation is clearly warranted into the pathophysiology of early failure.

We acknowledge the limitations of this study. There is a relatively small sample size, which might render the study underpowered to detect the impact of certain risk factors. In addition, this is a patient population who was selected for a continued endovascular approach and, therefore, may possess risk factors not known or measured in this study. Finally, this study design does not allow direct comparisons to a group of patients who underwent surgical or medical therapy after initial endovascular failure, and clinicians must continue to tailor therapy to individual patients.

CONCLUSIONS

SPTAS can be achieved with excellent technical success and low morbidity. However, these data suggest that SPTAS is not effective in establishing durable patency after initial failure of endovascular therapy, as midterm patency is limited and further reintervention is often required. In particular, failure within 180 days of the initial endovascular intervention portends very poor outcomes with SPTAS and thus identifies a group of patients in whom a continued endovascular approach is fruitless. Further studies are required to understand the pathophysiology of failure of endovascular therapy and to identify those patients at high risk for early failure. In addition, the clinical outcomes and cost-effectiveness of surgical therapy vs continued endovascular therapy in patients who fail an initial endovascular approach require further analysis.

AUTHOR CONTRIBUTIONS

Conception and design: WR, LN, MB
Analysis and interpretation: WR, LN, RB, MD
Data collection: WR, MB, RB
Writing the article: WR
Critical revision of the article: LN, RB, MB
Final approval of the article: WR, LN, RB, MB
Statistical analysis: LN, WR
Obtained funding: Not applicable
Overall responsibility: MB

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